

117TH CONGRESS
1ST SESSION

H. R. 3437

To require the Secretary of Health and Human Services to guarantee BioBonds in order to provide funding for loans to eligible biomedical companies and universities to carry out clinical trials approved by the Food and Drug Administration, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 20, 2021

Mr. RUSH (for himself, Mr. FITZPATRICK, Mr. BISHOP of Georgia, Mr. CARSON, Mr. COHEN, Mr. COOPER, Mr. DANNY K. DAVIS of Illinois, Mr. GRIJALVA, Mr. LEVIN of California, Mr. SCHNEIDER, Ms. SEWELL, and Mr. THOMPSON of Mississippi) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require the Secretary of Health and Human Services to guarantee BioBonds in order to provide funding for loans to eligible biomedical companies and universities to carry out clinical trials approved by the Food and Drug Administration, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-
2 tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Long-term Opportuni-
5 ties for Advancing New Studies for Biomedical Research
6 Act” or the “LOANS for Biomedical Research Act”.

1 **SEC. 2. BIOBONDS PROGRAM.**

2 (a) IN GENERAL.—Not later than 180 days after the
3 date of enactment of this Act, the Secretary of Health and
4 Human Services, in consultation with the Secretary of the
5 Treasury, shall establish a program, to be known as the
6 “Biobonds Program”, to increase innovative biomedical
7 research into therapies to address unmet medical needs,
8 under which biomedical researchers seeking to conduct
9 clinical trials with respect to a drug or device, but who
10 cannot secure appropriate funding to conduct such trials
11 (as determined by the Secretary of the Treasury), receive
12 financial assistance through—

13 (1) the purchasing of loans by fiscal agents
14 under section 3; and

15 (2) the sale and guarantee of Biobonds com-
16 prised of these loans under section 4.

17 (b) BIOMEDICAL RESEARCHERS ELIGIBLE FOR FI-
18 NANCIAL ASSISTANCE.—

19 (1) IN GENERAL.—A person shall be eligible to
20 receive a loan under the Biobonds Program if such
21 person is conducting or seeking to conduct research
22 with respect to a drug or device that is—

23 (A) intended for use to meet an unmet
24 medical need (as determined by the Secretary of
25 Health and Human Services); and

(B) under investigation in a controlled clinical trial under—

17 SEC. 3. PURCHASE OF LOANS BY FISCAL AGENTS.

18 (a) IN GENERAL.—Fiscal agents shall purchase
19 loans—

20 (1) made to an eligible recipient for the purpose
21 of conducting the applicable clinical trial; and

1 and not on the prospects for success of the clinical
2 trial.

3 (b) PRIORITY FOR LOANS.—The Secretary of Health
4 and Human Services shall issue rules to require fiscal
5 agents, in purchasing loans under this section, to—

6 (1) purchase loans with respect to a diverse
7 range of biomedical projects and not to favor one
8 disease or disability, but with priority given to loans
9 with potential to address unmet public health needs
10 across the spectrum of diseases and disabilities;

11 (2) consider as an important criterion for pur-
12 chasing loans with respect to clinical trials that they
13 are being conducted by women researchers or re-
14 searchers who are members of a racial and ethnic
15 minority group or disabled; and

16 (3) prioritize purchasing loans with respect to
17 clinical trials that include, where appropriate, rep-
18 resentative levels of women, members of a racial and
19 ethnic minority groups, disabled individuals, and
20 other diverse participants, as specified in guidance
21 issued under section 505(b) of the Federal Food,
22 Drug, and Cosmetic Act.

23 (c) MAXIMUM LOAN AMOUNT.—A fiscal agent may
24 not purchase loans in any one year with respect to a single
25 recipient in an amount more than \$25,000,000.

1 (d) LOAN TERMS AND CONDITIONS.—The Secretary
2 of Health and Human Services, in consultation with the
3 Secretary of the Treasury, shall issue rules to—

4 (1) establish criteria for the terms for loans
5 that are eligible for purchase under this section;

6 (2) establish criteria for the interest rate for
7 loans that are eligible for purchase under this sec-
8 tion, which shall be based on applicable rates for ob-
9 ligations of the Department of the Treasury of com-
10 parable maturity plus a rate to be determined by the
11 Secretary of the Treasury to reflect—

12 (A) prevailing market conditions;

13 (B) taxpayer protection; and

14 (C) the need to ensure ample funding for
15 clinical trials described under section 2; and

16 (3) permit the use of warrants and similar in-
17 struments with respect to loans that are eligible for
18 purchase under this section, where necessary to pro-
19 tect taxpayer interests.

20 **SEC. 4. BIOBONDS.**

21 (a) ISSUANCE.—The fiscal agents shall issue bonds,
22 to be known as “BioBonds”, collateralized by loans pur-
23 chased under this Act, and sell the BioBonds to investors.

24 (b) BIOBOND GUARANTEE.—The Secretary of
25 Health and Human Services shall provide a guarantee on

1 the payment of principal (but not the payment of interest)
2 for each BioBond, on a bond-by-bond basis, in an amount
3 to be determined by the Secretary, but in no case may
4 the amount of such guarantee be more than 90 percent
5 of the principal of the BioBond.

6 (c) SIZE OF ISSUANCES.—The Secretary of Health
7 and Human Services, in consultation with the Secretary
8 of the Treasury, shall establish the size of each BioBond
9 issuance, to ensure market acceptance, portfolio diver-
10 sification, and the protection of taxpayer interests.

11 (d) AUCTIONS.—The Secretary of Health and
12 Human Services may—

13 (1) authorize fiscal agents to use an auction to
14 select the purchasers of BioBonds; and

15 (2) require such auction to include a process
16 that minimizes the risk to the Government of the
17 Federal guarantee involved by allowing bidders for a
18 BioBond to compete against each other by bidding
19 on the percentage of the Federal guarantee under
20 subsection (b) with respect to the BioBond, with the
21 bid for the lowest percentage winning the auction,
22 taking into account other terms and conditions set
23 by the issuer to ensure the lowest total cost to the
24 Government.

1 (e) PORTFOLIO DIVERSITY.—With respect to an
2 issuance of BioBonds and the loans collateralizing such
3 issuance, no more than 15 percent of the principal amount
4 of such issuance may relate to a group of related diseases
5 or disabilities (as defined by the Secretary of Health and
6 Human Services).

7 (f) PRIORITIZATION OF TAXPAYER INTERESTS.—All
8 BioBonds shall be structured to give first priority to pro-
9 tecting the interests of the United States by ensuring
10 that—

11 (1) all cash proceeds received from the repay-
12 ment of a BioBond are first used to reduce the
13 amount of principal guaranteed by the Secretary of
14 Health and Human Services; and

15 (2) the Secretary of Health and Human Serv-
16 ices has a senior claim on all assets and collateral
17 under a BioBond to the extent the guarantee pro-
18 vided by the Secretary is not extinguished.

19 **SEC. 5. FISCAL AGENTS.**

20 (a) IN GENERAL.—The Secretary of the Treasury
21 shall contract with institutions to carry out the duties of
22 fiscal agents under this Act, under such criteria as the
23 Secretary of Health and Human Services, in consultation
24 with the Secretary of the Treasury, determines appro-
25 priate.

1 (b) SOUND UNDERWRITING PRACTICES.—The Sec-
2 retary of the Treasury shall issue rules to ensure that fis-
3 cal agents use sound underwriting practices that protect
4 the interests of—

5 (1) the United States;
6 (2) BioBond investors; and
7 (3) the long-term promotion of innovative bio-
8 medical research into therapies to address unmet
9 medical needs.

10 (c) COMPENSATION.—A fiscal agent shall be com-
11 pensated for performing duties under this Act from the
12 proceeds from the sale of Biobonds issued by the fiscal
13 agent, at such rate and on such terms as the Secretary
14 of the Treasury may provide.

15 (d) RULEMAKING.—Not later than 180 days after the
16 date of enactment of this Act, the Secretary of the Treas-
17 ury shall issue final rules to carry out this section.

18 **SEC. 6. REPORTS.**

19 (a) GAO STUDY AND REPORTS ON OTHER RE-
20 SEARCH PROJECTS.—

21 (1) ONGOING STUDY.—The Comptroller Gen-
22 eral of the United States shall carry out an ongoing
23 study to consider whether a program similar to the
24 BioBonds Program should be established for other
25 biomedical research projects.

1 (2) REPORT.—The Comptroller General shall
2 issue a report to the Congress, not less frequently
3 than annually, on all findings and determinations
4 made in carrying out the study required under para-
5 graph (1).

6 (b) REPORTS ON THE BIOBONDS PROGRAM.—Not
7 later than 2 years after the date on which BioBonds are
8 first issued, and annually thereafter during the period
9 ending on the date that is 4 years after the date on which
10 BioBonds are first issued, the Comptroller General and
11 the Secretary of Health and Human Services shall each
12 issue a separate report to the Congress on—

13 (1) the progress of the issuance of BioBonds;
14 (2) the reasons for any problems achieving de-
15 sired volumes of BioBonds or the ability of the Pro-
16 gram to proceed at a faster pace;

17 (3) an analysis of the risk to the Government
18 in providing the Federal guarantee described under
19 section 4(b);

20 (4) any recommended improvements to the Pro-
21 gram; and

22 (5) any other matter that the Comptroller Gen-
23 eral or the Secretary, respectively, determines is ap-
24 propriate.

1 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

2 (a) IN GENERAL.—There is authorized to be appro-
3 priated to the Secretary of Health and Human Services
4 to pay for the cost of guaranteeing BioBonds under this
5 Act \$10,000,000,000 for each of fiscal years 2022, 2023,
6 and 2024.

7 (b) PROGRAM FUNDING.—

8 (1) ADMINISTRATIVE EXPENSES PAID FROM
9 BOND SALES.—Except as provided under paragraph
10 (2), the cost of carrying out this Act, including the
11 cost to the Secretary of Health and Human Services
12 in administering the BioBond Program, shall be re-
13 covered from the proceeds from the sale of BioBonds
14 or from fees as set forth in paragraph (3).

15 (2) SPECIFIC APPROPRIATION OR CONTRIBU-
16 TION.—No guarantee shall be made under this Act
17 unless—

18 (A) an appropriation for the full cost of
19 the guarantee has been made;

20 (B) the Secretary has received from the
21 BioBond issuer a payment in full for the cost
22 of the guarantee; or

23 (C) a combination of an appropriation and
24 the deposit of a payment from the bond issuer
25 into the Treasury has been made in a sufficient
26 amount to cover the full cost of the guarantee.

1 (3) COST OF GUARANTEES.—

2 (A) IN GENERAL.—The Secretary of
3 Health and Human Services shall charge and
4 collect fees for guarantees under this Act in
5 amounts the Secretary determines are sufficient
6 to recover applicable administrative expenses.

7 (B) AVAILABILITY.—Fees collected under
8 this subsection—

- 9 (i) shall be deposited by the Secretary
10 into the Treasury; and
11 (ii) are authorized to remain available
12 until expended.

13 **SEC. 8. DEFINITIONS.**

14 In this Act:

15 (1) COST.—The term “cost” has the meaning
16 given to the term “cost of a loan guarantee” in sec-
17 tion 502(5)(C) of the Federal Credit Reform Act of
18 1990 (2 U.S.C. 661a(5)(C)).

19 (2) ELIGIBLE RECIPIENT.—The term “eligible
20 recipient” means a person described under section
21 2(b).

22 (3) FISCAL AGENT.—The term “fiscal agent”
23 means a person selected as a fiscal agent under sec-
24 tion 5(a).

